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| **CRITICALLY APPRAISED TOPIC** |

**FOCUSED CLINICAL QUESTION**

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| For middle-aged adults with hemiplegia following a CVA who require physical assistance to stand and take steps, does body weight supported treadmill training, overground gait training or a combination of the two interventions lead to the greatest locomotor recovery? |

**AUTHOR**

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**CLINICAL SCENARIO**

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| A 48-year-old female patient with severe left hemiplegia and speech deficit following a CVA lives with her husband, who is her primary caretaker, and she requires his assistance with all transfers and to propel her wheelchair. Her goal and that of her husband is for her to return to independent ambulation. In the clinic, the patient can take 1-2 steps using a hemiwalker even with maximum assistance x 2 because she requires her left knee to be blocked, which limits her ability to advance the paretic limb. Application of a knee brace locking her affected limb into extension has not increased the number of steps she could take using a hemiwalker. The clinic possesses a harness system for body weight supported treadmill training (BWSTT), but therapists have not yet tried this technique to facilitate a stepping pattern with this patient. This patient’s physical therapists and other clinicians with similar cases will benefit from the ability to discern whether or not BWSTT would confer a benefit over more traditional overground gait training methods in helping this patient recover her ability to initiate stepping and recover independent ambulation. |

**SUMMARY OF SEARCH**

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| * A total of 16 studies were selected that met the inclusion/exclusion criteria, including 14 randomized controlled trials (RCT) and two systematic reviews with meta-analyses. Three studies—two RCTs and one systematic review--were selected as “best evidence” based on relevance to the clinical question and methodological quality, and they were reviewed and discussed. Since the systematic review was the most recent and included consideration of the two RCTs, greater weight was given to its outcomes. * For individuals with hemiparesis following stroke who are dependent on assistance to walk at baseline, body weight supported treadmill training (BWSTT) generally improves walking ability but does not result in statistically significant higher numbers of people achieving independent walking when compared to other physical therapy interventions, including overground walking training. On the other hand, among patients with stroke who are initially able to walk independently, BWSTT results in statistically significant greater improvement in walking speed and endurance compared to other physical therapy methods; however, these benefits are of minimal clinical importance. * In future research, RCTs of large sample size and high methodological rigor should examine the impact of combined locomotor interventions such as BWSTT with overground walking compared with either intervention alone. Since protocols of trials examining the impact of BWSTT have to date varied widely, further investigation of treadmill training interventions should examine the impact of difference frequencies and durations of training as well as use of handrails on walking outcomes. |

**CLINICAL BOTTOM LINE**

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| Considered together, best evidence suggests that while treadmill training with partial body weight support is safe and will likely lead to improvement in walking ability for patients with hemiparesis following stroke, it does not offer a significant advantage over other physical therapy interventions when the patient is nonambulatory at baseline. However, for a subgroup that is ambulatory at baseline, it may offer a small advantage in improving walking speed and endurance. Therapists considering best method for walking rehabilitation for individual patients in this population should inform patients of these findings and then base decisions on equipment and staff availability, difficulty of mobilising the patient overground, and patient preference. |

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| ***This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor*** |

**SEARCH STRATEGY**

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| **Terms used to guide the search strategy** | | | |
| **P**atient/Client Group | **I**ntervention (or Assessment) | **C**omparison | **O**utcome(s) |
| Stroke  stroke [Mesh]  CVA  cerebrovascular accident  hemiparesis | treadmill training  locomotor training  body weight support\*  body weight supported treadmill training  body-weight supported treadmill training  body-weight-supported treadmill training  body weight-supported treadmill training  treadmill training with partial body weight support | physical therapy  physiotherapy  rehabilitation  (gait OR walk\*)  overground walking | walking ability  ambulat\*  gait  locomotor recovery  locomotor function |

**Final search strategy:**

**PubMed:**

#1 Search stroke OR CVA OR cerebrovascular accident

#2 Search “Stroke” [Mesh]

#3 Search locomotor training OR body weight support\* OR body weight supported treadmill training OR treadmill training with partial body weight support OR body-weight-supported treadmill training OR body weight-supported treadmill training

#4 Search (physical therapy OR physiotherapy OR rehabilitation) AND (gait or walk\*)

#5 Search walking ability OR ambulat\* OR gait OR locomotor recovery OR locomotor function

#6 Search “Gait” [Mesh]

#7 Search #1 OR #2

#8 Search #5 OR #6

#9 Search #3 AND #4 AND #7 AND #8

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| **Databases and Sites Searched** | **Number of results** | **Limits applied, revised number of results (if applicable)** |
| **PubMed** | **320** | **167:** Revised number of results after applying the “Article Types” filters “Clinical trial” (122) and “Review” (45) |
| **CINAHL** | **195** | **156:** Revised number after limiting to the major subheadings “stroke” and source type “academic journals”  **36:** Further reduced number after further limiting to second major subheading of “walking” |
| **Cochrane Library** | **170** | **96:** Limited to Cochrane “Review” (versus “all” including protocols) plus another 56 under “Trials” |
| **PEDro** | **22** | Reduced original search strategy to key words “stroke AND body weight supported treadmill training” |
| **Reference Search** | **1** | The Ada 2010 study was found through the reference list of a retrieved article and was not included among articles retrieved through the above database searches |

## INCLUSION and EXCLUSION CRITERIA

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| **Inclusion Criteria** |
| * Published in English * Randomized controlled trials, controlled trials, uncontrolled trials, or systematic reviews * Published up to September 2014 * Interventions that included either body weight supported treadmill training or overground walking training or comparison of the two * Studied an adult population poststroke, preferably with hemiparesis/hemiplegia * Subjects required physical assistance to stand or ambulate at baseline prior to ambulation with or without a device * Measured gait characteristics or waking ability with or without device before and after intervention |
| **Exclusion Criteria** |
| * Studies that utilized robotic-assistance locomotor training, functional electrical stimulation combined with the body weight supported treadmill or overground training * Studied children or adults with cerebral palsy (prenatal stroke), even if they demonstrate hemiparesis and gait dysfunction * Levels of evidence 3-5 in the hierarchy: i.e., case studies, case series, qualitative studies, narrative review articles, expert opinion papers, dissertations |

**RESULTS OF SEARCH**

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| A total of | 16 | relevant studies were located and categorised as shown in the following table (based on Levels of Evidence, Centre for Evidence Based Medicine, 2011) using the PEDro quality assessment rating scale for RCTs and qualitative analyses based on the Quality Appraisal Checklist (Jewell 2009) for systematic reviews. |

**Summary of articles retrieved that met inclusion and exclusion criteria**

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| --- | --- | --- | --- |
| **Author (Year)** | **Study quality score** | **Level of Evidence** | **Study design** |
| Ada L, Dean CM, Morris ME, Simpson JM, & Katrak P. (2010) | **9/11** | **1b** | **Randomized controlled trial** |
| Barbeau H & Visintin M (2003) | **5/11** | **1b** | **Randomized controlled trial** |
| Combs-Miller SA, Kalpathi Parameswaran A, Colburn D, Ertel T, Harmeyer A, Tucker L, Schmid AA. (2014) | **8/11** | **1b** | **Randomized controlled trial** |
| Dean CM, Ada L, Bampton J, Morris ME, Katrak PH, Potts S. (2010) | **9/11** | **1b** | **Randomized controlled trial** |
| DePaul VG, Wishart LR, Richardson J, Thabane L, Ma J, Lee TD. (2014) | **9/11** | **1b** | **Randomized controlled trial** |
| [Duncan PW](http://www.ncbi.nlm.nih.gov/pubmed?term=Duncan%20PW%5BAuthor%5D&cauthor=true&cauthor_uid=21612471), [Sullivan KJ](http://www.ncbi.nlm.nih.gov/pubmed?term=Sullivan%20KJ%5BAuthor%5D&cauthor=true&cauthor_uid=21612471), [Behrman AL](http://www.ncbi.nlm.nih.gov/pubmed?term=Behrman%20AL%5BAuthor%5D&cauthor=true&cauthor_uid=21612471), [Azen SP](http://www.ncbi.nlm.nih.gov/pubmed?term=Azen%20SP%5BAuthor%5D&cauthor=true&cauthor_uid=21612471), [Wu SS](http://www.ncbi.nlm.nih.gov/pubmed?term=Wu%20SS%5BAuthor%5D&cauthor=true&cauthor_uid=21612471), [Nadeau SE](http://www.ncbi.nlm.nih.gov/pubmed?term=Nadeau%20SE%5BAuthor%5D&cauthor=true&cauthor_uid=21612471), [Dobkin BH](http://www.ncbi.nlm.nih.gov/pubmed?term=Dobkin%20BH%5BAuthor%5D&cauthor=true&cauthor_uid=21612471), [Rose DK](http://www.ncbi.nlm.nih.gov/pubmed?term=Rose%20DK%5BAuthor%5D&cauthor=true&cauthor_uid=21612471), [Tilson JK](http://www.ncbi.nlm.nih.gov/pubmed?term=Tilson%20JK%5BAuthor%5D&cauthor=true&cauthor_uid=21612471), [Cen S](http://www.ncbi.nlm.nih.gov/pubmed?term=Cen%20S%5BAuthor%5D&cauthor=true&cauthor_uid=21612471), [Hayden SK](http://www.ncbi.nlm.nih.gov/pubmed?term=Hayden%20SK%5BAuthor%5D&cauthor=true&cauthor_uid=21612471). (2011) | **8/11** | **1b** | **Randomized controlled trial** |
| Franceschini M, Carda S, Agosti M, Antenucci R, Malgrati D, Cisari C; Gruppo Italiano Studio Allevio Carico Ictus. (2009) | **6/11** | **1b** | **Randomized controlled trial** |
| Høyer E, Jahnsen R, Stanghelle JK, Strand LI. (2012) | **8/11** | **1b** | **Randomized controlled trial** |
| Kosak M, Reding M. (2000) | **5/11** | **1b** | **Randomized controlled trial** |
| [Mackay-Lyons M](http://www.ncbi.nlm.nih.gov/pubmed?term=Mackay-Lyons%20M%5BAuthor%5D&cauthor=true&cauthor_uid=23599221), [McDonald A](http://www.ncbi.nlm.nih.gov/pubmed?term=McDonald%20A%5BAuthor%5D&cauthor=true&cauthor_uid=23599221), [Matheson J](http://www.ncbi.nlm.nih.gov/pubmed?term=Matheson%20J%5BAuthor%5D&cauthor=true&cauthor_uid=23599221), [Eskes G](http://www.ncbi.nlm.nih.gov/pubmed?term=Eskes%20G%5BAuthor%5D&cauthor=true&cauthor_uid=23599221), [Klus MA](http://www.ncbi.nlm.nih.gov/pubmed?term=Klus%20MA%5BAuthor%5D&cauthor=true&cauthor_uid=23599221). [Mackay-Lyons M](http://www.ncbi.nlm.nih.gov/pubmed?term=Mackay-Lyons%20M%5BAuthor%5D&cauthor=true&cauthor_uid=23599221), [McDonald A](http://www.ncbi.nlm.nih.gov/pubmed?term=McDonald%20A%5BAuthor%5D&cauthor=true&cauthor_uid=23599221), [Matheson J](http://www.ncbi.nlm.nih.gov/pubmed?term=Matheson%20J%5BAuthor%5D&cauthor=true&cauthor_uid=23599221), [Eskes G](http://www.ncbi.nlm.nih.gov/pubmed?term=Eskes%20G%5BAuthor%5D&cauthor=true&cauthor_uid=23599221), [Klus MA](http://www.ncbi.nlm.nih.gov/pubmed?term=Klus%20MA%5BAuthor%5D&cauthor=true&cauthor_uid=23599221). (2013) | **9/11** | **1b** | **Randomized controlled trial** |
| [Mehrholz J](http://www.ncbi.nlm.nih.gov/pubmed?term=Mehrholz%20J%5BAuthor%5D&cauthor=true&cauthor_uid=24458944), [Pohl M](http://www.ncbi.nlm.nih.gov/pubmed?term=Pohl%20M%5BAuthor%5D&cauthor=true&cauthor_uid=24458944), [Elsner B](http://www.ncbi.nlm.nih.gov/pubmed?term=Elsner%20B%5BAuthor%5D&cauthor=true&cauthor_uid=24458944). (2014) | **High quality**: Authors limited to RCTs, included grey literature and non-English studies and determined no publication bias, fully described study selection and search methods, assessed quality by analyzing level of risk of testing and assignment bias, reported pooled effect sizes and risk differences/ratios for all major outcomes via several subgroup analyses based on heterogeneity of treatment design and participantsusing individual subject data. They used random effects model of analysis since parameters of interventions varied between studies. They compared their findings with other available comparable reviews; theirs was a more comprehensive review. | **1a** | **Systematic Review with meta-analysis** |
| [Nilsson L](http://www.ncbi.nlm.nih.gov/pubmed?term=Nilsson%20L%5BAuthor%5D&cauthor=true&cauthor_uid=11594641), [Carlsson J](http://www.ncbi.nlm.nih.gov/pubmed?term=Carlsson%20J%5BAuthor%5D&cauthor=true&cauthor_uid=11594641), [Danielsson A](http://www.ncbi.nlm.nih.gov/pubmed?term=Danielsson%20A%5BAuthor%5D&cauthor=true&cauthor_uid=11594641), [Fugl-Meyer A](http://www.ncbi.nlm.nih.gov/pubmed?term=Fugl-Meyer%20A%5BAuthor%5D&cauthor=true&cauthor_uid=11594641), [Hellström K](http://www.ncbi.nlm.nih.gov/pubmed?term=Hellstr%C3%B6m%20K%5BAuthor%5D&cauthor=true&cauthor_uid=11594641), [Kristensen L](http://www.ncbi.nlm.nih.gov/pubmed?term=Kristensen%20L%5BAuthor%5D&cauthor=true&cauthor_uid=11594641), [Sjölund B](http://www.ncbi.nlm.nih.gov/pubmed?term=Sj%C3%B6lund%20B%5BAuthor%5D&cauthor=true&cauthor_uid=11594641), [Sunnerhagen KS](http://www.ncbi.nlm.nih.gov/pubmed?term=Sunnerhagen%20KS%5BAuthor%5D&cauthor=true&cauthor_uid=11594641), [Grimby G](http://www.ncbi.nlm.nih.gov/pubmed?term=Grimby%20G%5BAuthor%5D&cauthor=true&cauthor_uid=11594641). (2001) | **6/11** | **1b** | **Randomized controlled trial** |
| Van Peppen RP, Kwakkel G, Wood-Dauphinee S, Hendriks HJ, Van der Wees PJ, Dekker J. (2004) | **Moderate to low quality**: Authors included CCTs and RCTs, did not include grey literature and limited non-English studies to German or Dutch; failed to address publication bias; clearly described study selection criteria and search methods but did not include copies of search strategy; assessed quality using the PEDro scale for all included studies and included explanation of their ratings of levels of quality per score; used study data versus individual patient data in calculations of pooled effects; reported pooled effect sizes for the body weight supported treadmill training subgroup (only 5 RCTs and 2 CCTs) using the fixed effects model of analysis, assuming relative homogeneity in treatment effect and outcome measure; failed to compare their findings with other available comparable reviews. | **1a** | **Systematic Review with multiple subgroup meta-analyses by type of stroke therapy** |
| [Visintin M](http://www.ncbi.nlm.nih.gov/pubmed?term=Visintin%20M%5BAuthor%5D&cauthor=true&cauthor_uid=9626282), [Barbeau H](http://www.ncbi.nlm.nih.gov/pubmed?term=Barbeau%20H%5BAuthor%5D&cauthor=true&cauthor_uid=9626282), [Korner-Bitensky N](http://www.ncbi.nlm.nih.gov/pubmed?term=Korner-Bitensky%20N%5BAuthor%5D&cauthor=true&cauthor_uid=9626282), [Mayo NE](http://www.ncbi.nlm.nih.gov/pubmed?term=Mayo%20NE%5BAuthor%5D&cauthor=true&cauthor_uid=9626282). (1998) | **6/11** | **1b** | **Randomized controlled trial** |
| Werner C, Bardeleben A, Mauritz KH, Kirker S, Hesse S. (2002) | **8/11** | **1b** | **Randomized controlled trial** |
| [Yen CL](http://www.ncbi.nlm.nih.gov/pubmed?term=Yen%20CL%5BAuthor%5D&cauthor=true&cauthor_uid=17507641), [Wang RY](http://www.ncbi.nlm.nih.gov/pubmed?term=Wang%20RY%5BAuthor%5D&cauthor=true&cauthor_uid=17507641), [Liao KK](http://www.ncbi.nlm.nih.gov/pubmed?term=Liao%20KK%5BAuthor%5D&cauthor=true&cauthor_uid=17507641), [Huang CC](http://www.ncbi.nlm.nih.gov/pubmed?term=Huang%20CC%5BAuthor%5D&cauthor=true&cauthor_uid=17507641), [Yang YR](http://www.ncbi.nlm.nih.gov/pubmed?term=Yang%20YR%5BAuthor%5D&cauthor=true&cauthor_uid=17507641). (2008) | **8/11** | **1b** | **Randomized controlled trial** |

**BEST EVIDENCE**

The following 3 studies were identified as the ‘best’ evidence and selected for critical appraisal. Reasons for selecting these studies were:

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| * **Ada 2010:** This RCT was among those with the highest methodological quality of the studies meeting the inclusion/exclusion criteria. The investigators managed the groups similarly, ensuring equal amount of overall physical therapy session time (30 min/day) allotted to overground gait training or body weight supported treadmill training (BWSTT) and allowing only one therapist to assist individual subjects in either group; such controls allow the experimental effect to be more effectively isolated and improve the internal validity of the study. The degree of detail with which the study protocol was described makes it easy to reproduce or modify as needed with patients. Furthermore, the primary outcomes are all inherently clinically meaningful: whether or not the patient becomes independent in walking (which is the primary outcome goal for the patient described in the clinical question) and the number of participants in each group discharged to supported accommodations (e.g., nursing homes) versus home. Perhaps most importantly, the fact that the intervention was provided early after stroke and to a population nonambulatory at baseline makes results more applicable to the clinical scenario patient for whom therapists were considering BWSTT than many of the other studies.Secondary outcomes associated with this trial, including walking speed and endurance, are also available and supplied in the companion publication by Dean at al (2010). * **Barbeau 2003:** This paper includes additional analysis of data collected from the trial originally performed by Visinton et al (1998).The main goals of the study included determining the characteristics of stroke patients likely to benefit from BWSTT and also the carryover of treadmill walking to overground outcomes. These are arguably even more important considerations for a therapist versus whether an individual can make “statistically significant” gains in speed or endurance compared to other interventions (the focus of many other studies). They stratified subjects according to ambulatory status prior to randomization. The “low” group corresponds with the clinical scenario patient case since these participants are classified as nonambulatory or requiring maximum assistance. Although it is not without its methodological flaws and is an older study, authors include a great deal of detail regarding the study protocol and the sample size is large, which improves internal validity. * **Mehrholz 2014:** This systematic review was of excellent methodological quality as described in the table above. The meta-analyses allow inclusion of exponentially higher number of subjects compared to single RCTs and thus more meaningful effect sizes of pooled outcomes may be determined. By breaking included studies into subgroups, this study allows therapists to consider comparisons between the outcomes of BWSTT compared to other physical therapy as well as to treadmill training supplied without body weight support. Analyses within these categories are further broken down by degree of severity of gait impairment at baseline (ambulatory or not) and length of time since stroke. This allows a therapist to match treatment considerations to the characteristics of a patient and consider a wider range of options suitable for her plan of care and how they compare to BWSTT. Furthermore, the primary outcomes considered by authors across all subgroups are those of greatest interest for the clinical scenario patient: walking ability (measured by level of independence), walking speed and walking endurance. |

**SUMMARY OF BEST EVIDENCE**

**(1) Description and appraisal of *Randomized trial of treadmill walking with body weight support to establish walking in subacute stroke: the MOBILISE trial* by Ada et al. (2010)**

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| **Aim/Objective of the Study/Systematic Review:** |
| The objective was to determine whether treadmill training with partial body weight support leads to independent walking earlier or more consistently than overground walking training for individuals with hemiparesis following stroke who are nonambulatory at baseline. |
| **Study Design** |
| * A multicentre, assessor-blinded randomized controlled trial * Subjects constituted a convenience sample recruited to the study between August 2002 and September 2008 * Subjects were screened by an outside recruiter and stratified by severity and center in random blocks of 4-6 individuals * Severity for purposes of stratification was determined by sitting balance according to the Motor Assessment Scale for stroke * Subjects were randomly assigned to an experimental or control group using a concealed allocation procedure * Before the study started, the allocation sequence was computer generated and located at a central office later contacted to ensure randomization was secure * Outcome measures were collected weekly until subject could walk independently or was discharged from the hospital and 6 months from initiation of the study * Blinding of the assessor was certified by the following process: assessors worked at a site outside the therapy area, subjects were asked to withhold information from assessors about the intervention they were receiving, and measures were taken outside of therapy hours. * Intention-to-treat data analysis using the Kaplan-Meier survival curve method was employed. * A blinded biostatistician performed all survival analyses * A priori power calculation was conducted to determine sample size, and the study was designed to detect a 25% increase (from 50% to 75%) in the proportion of nonambulatory patients walking independently with 80% power and 5% two-tailed significance level. |
| **Setting** |
| Subjects received treatment in rehabilitation units at 6 different hospitals, 3 of which had an on-site acute stroke unit and 1 of which had close ties with an acute stroke unit off-site. |
| **Participants** |
| * 126 total subjects recruited to the study. Experimental group: N = 64. Control group: N=62 * Method of recruitment: while authors did not state method explicitly, their interest in the rehabilitation units having a relationship with acute stroke units implies subjects were recruited from acute stroke units in affiliated hospitals. * Inclusion criteria for subjects: within 4 months of a first stroke, 50-85 years of age, diagnosed with hemiparesis/hemiplegia, nonambulatory (defined as a score of 0 or 1 on item 5, “walking”, on the Motor Assessment Scale for Stroke) * Exclusion criteria for subjects: clinical manifestations of brain stem lesions, severe cognitive or language impairments limiting ability to comprehend/follow instructions, unstable cardiac conditions, any pre-existing comorbidities making them inappropriate candidates for rehab * Nottingham Sensory Assessment, line bisection test and Ashworth Scale were utilized to detect existence of any concurrent sensory loss, spasticity or unilateral neglect, and the results were recorded for each patient * Gender: 55 female, 71 male * Mean age: 71 years (SD 9) * Mean time between stroke and entry into study: 17 days (SD 7) * 4 participants died (2 from experimental and 2 from control group); 2 withdrew (both from experimental group) * At baseline, groups were similar on all key demographics: age, gender, days between stroke and admission to study, side of hemiparesis, sitting balance score on Motor Assessment Scale for Stroke, and impairments (sensory loss, spasticity, and neglect) * Number of participants per group was similar at the different centers * Available for follow-up: 60 participants in each group, experimental and control |
| **Intervention Investigated** |
| *Control* |
| * Control subjects completed 30 minutes per day maximum overground walking practice 5 days per week with one therapist’s assistance; this intervention time was measured from participant coming out of the wheelchair to returning to the wheelchair (including donning assistive devices, transfers and rest breaks) * Other lower extremity physical therapy interventions were limited to a maximum of 60 minutes per day, but no other part of the rehabilitation program was controlled * Walking aids allowed included knee splints, ankle-foot orthoses, parallel bars, platform walker, or walking sticks * If unable to walk with the therapist’s assistance, participants practiced weight shifting or stepping forward and backward. * Once able to walk with assistance, participants were encouraged to increase speed, plus assistance from therapist and devices were reduced. * Therapists logged use of aids, distance walked, and assistance required for each walking session. |
| *Experimental* |
| * Experimental subjects completed 30 minutes per day walking on a treadmill with weight supported by a body harness 5 days per week with one therapist’s assistance; this intervention time was measured from participant coming out of the wheelchair to returning to the wheelchair (including setup, donning assistive devices, transfers and rest breaks) * Other lower extremity physical therapy interventions were limited to a maximum of 60 minutes per day, but no other part of the rehabilitation program was controlled * Initial body weight was individualized such that the participant’s knee in midstance was 15 degrees or less from full extension. * Initial treadmill speed was set for achievement of regular step length while also allowing time for the therapist to assist the hemiparetic limb through swing phase. If unable to walk on the moving treadmill with the therapist’s assistance, participants walked in place. * Therapists reduced body weight support according to the following previously published guidelines: 1) help no longer required for swing-through of hemiparetic limb, 2) full extension without hyperextension maintained through stance phase, 3) help not required for adequate step length * Overground walking for 10 minutes was included in the treatment time once a speed of 0.4 m/sec without body weight support was achieved on the treadmill * Therapists logged treadmill speed and amount of weight support, use of aids, distance walked, and assistance required for each walking session. |
| **Outcome Measures** (Primary and Secondary) |
| * Primary outcome measure: percentage of participants (0-100%) able to walk independently within 6 months. Independent walking is defined for this study as able to walk 15 m continuously across flat surface barefoot without any walking aids. * Participants were tested once per week before intervention outside the therapy area by a blinded assessor throughout the total treatment period until either independent walking was achieved or they were discharged, and again at 6 months after initiation of intervention.   Secondary outcomes are reported in another paper presented by Dean et al (2010). |
| **Main Findings** |
| * In week 1, 129m (interquartile range [IQR], 77-203) median distance per session of walking was performed by the experimental group versus 26 m (IQR, 1-77) by the control group. (control group distance ~20% of experimental distance) * In the final week of training, the median distance per walked per session was 254 m (IQR, 164-485) by the experimental group versus 120m (IQR, 73-227) by the control group. (control group distance ~47% of experimental difference) * Within 6 months of treatment initiation, 43/60 experimental group subjects walked independently compared with 36/60 control group participants. * At the end of 1 month of intervention, 37% of experimental and 26% of control group members were able to walk independently; at 2 months 66% of experimental compared with 55% of control participants; at 6 months, 71% experimental compared with 60% of control subjects. All of these proportions were calculated using Kaplan-Meier estimates. * The between-groups difference in proportion of subjects walking independently from 4 weeks to 6 months did not reach statistical significance: log-rank X2=1.77; P=0.13. * The mean time taken to walk independently for the experimental group (ie, the time required for 50% of the group to achieve independent walking) was 5 weeks; for the control group, the mean time was 7 weeks. * 9/60 experimental group participants were discharged to living situations requiring formal support (eg, nursing homes) compared to 18/62 control group participants. Between-groups risk difference = -14%; 95% CI= -28-1. |
| **Original Authors’ Conclusions** |
| Authors concluded that while differences between intervention groups were non-significant, body weight supported treadmill training resulted in more individuals (>10%) with hemiparesis post-stroke who were originally non-ambulatory being able to achieve independent walking compared with an assisted overground walking program. Additionally, those receiving body-weight supported treadmill training achieved independent walking 2 weeks earlier on average than those training overground. The earlier time to walking, in addition to 14% reduced discharge rate to supported living accommodations were determined by the authors to likely save healthcare expenditures on rehabilitation and costs to the community of long-term care. Authors reasoned that the differences in independent walking achieved between groups was due to the amount of training allowed by each method rather than the method itself, as body weight supported treadmill training allowed more overall distance to be covered per training session on average than overground training, and the literature supports that more intense training leads to greater success in outcomes. |
| **Critical Appraisal** |
| **Validity** |
| * PEDro Scale score: 8/11 based on eligibility criteria: Yes; Random Allocation: Yes; Concealed Allocation: Yes; Baseline Comparison: Yes; Blind Subjects: No; Blind Therapist: No; Blind Assessors: Yes; >85% participant outcomes: Yes; Intention-to-treat analysis: Yes; Between-group comparison: Yes; Point estimates and variability: Yes * Participants and therapists administering the walking interventions were not blinded and therefore could have biased the outcomes. * Intention-to-treat analysis was used to handle missing data and thus preserved the random allocation and similarity between groups. * Since subjects within the experimental and control groups did not all receive the same number of walking intervention sessions, a difference between groups could have existed in terms of average overall number of sessions completed prior to discharge, which could have introduced bias where independent walking was not achieved prior to discharge. * The use of survival statistics such as log-rank test appears appropriate for capturing the desired group comparisons in length of time until independent walking. * Finally, the authors noted the following as limitations to their own study: 1) difficult and lengthy recruitment process; 2) variations in numbers of participants from each center due to patient volume differences as well as centers joining the trial at different time points; 3) possible bias due to inability to blind therapists and participants; 4) need for a much greater sample size (>800) to achieve the power necessary to detect the resulting 11% difference (average among time points of walking assessment) between groups in ability to walk unaided. However, they characterized the multicentre nature of the design and the involvement of multiple therapists as strengths boosting external validity of their findings. |
| **Interpretation of Results** |
| Results slightly favour body weight supported treadmill training (BWSTT) versus overground training for an initially non-ambulatory population with hemiparesis when initiated shortly after stroke, as BWSTT led to more frequent and earlier independent walking in this trial. However, the differences in groups failed to reach statistical significance. In performing a priori calculations of optimal sample size, the authors powered the study to detect a 25% difference between groups, which would equate to a large effect size of 25% greater proportion in individuals who would walk independently by the end of 6 months. Since they only found an 11% difference at the end of the 6 months, a much smaller effect, the results were not statistically significant. Authors noted that more than 800 subjects would be needed to detect this smaller observed effect size. Therefore, the observed effect is unlikely to be clinically significant, suggesting both interventions may be viewed as equally effective in recovering independent walking.  The initial overall sample size came close to meeting their calculated need for 130 total participants and the loss to follow-up was fairly small (6/126 or 4.7%); it is therefore unlikely that these numbers made a difference statistically.  Risk difference between groups in terms of discharge to a supportive setting (nursing home, etc) also failed to reach significance since the confidence interval of -28-1 included 0.  Although they were all provided written guidelines describing progression and were trained in delivering both interventions, multiple therapists were employed in administering the intervention at the different sites. Differences in their levels of experience could have influenced how treatment was delivered, acting as a confounding variable. |

**(2) Description and appraisal of *Treadmill Training and Body Weight Support* for Walking after Stroke by Mehrholz et al (2014)**

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| **Aim/Objective of the Study/Systematic Review:** |
| The authors sought to determine through this literature review if treadmill training, body weight support, or a combination of the two, leads to improvement among patients undergoing rehabilitation following stroke in walking ability (primary outcome), quality of life, activities of daily living, institutionalization or death, and dependency or death compared with other gait training interventions provided by physical therapists. They also sought to discover whether or not treadmill training, body weight support or a combination is safe and well-tolerated as a gait training method (secondary outcomes). |
| **Study Design** |
| This study was a systematic review with primary and subgroup meta-analyses.  **Search Strategy:**   * The reviewers searched the Cochrane Stroke Group Trials Register (last searched June 2013) as well as many bibliographic databases: the Cochrane Central Register of Controlled Trials (CENTRAL) and the Database of Reviews of Effects (DARE) (The Cochrane Library 2013, Issue 7), MEDLINE (1966 to July 2013), EMBASE (1980 to July 2013), CINAHL (1982 to June 2013), AMED (1985 to July 2013) and SPORTDiscus (1949 to June 2013). * Reviewers also searched grey literature; they considered relevant conference proceedings and ongoing trials and research registers, screened reference lists of selected articles and contacted trialists, researchers and experts in this field. They included trial reports in all languages in their search and arranged for translation into English as needed.   **Selection Criteria:** Reviewers included truly randomised controlled trials and quasi-randomized controlled trials, including the first arm of data from cross-over designs. Treadmill training and/or body weight support of any intensity and duration had to have been included in one of the experimental conditions for at least one treatment session, and trials were sorted according to the following comparisons:   * Treadmill training with body weight support versus other physical therapy, no treatment or placebo * Treadmill training without body weight support versus other physical therapy, no treatment or placebo * Treadmill training with body weight support versus treadmill training without body weight support * Body weight support (without treadmill training) versus other physical therapy, no treatment or placebo   Trials in which treadmill training, body weight support or a combination of the two were combined with other physical therapy co-interventions where the co-interventions for the experimental and control groups were similar were grouped according to the categories above. However, trials in which the co-interventions were not similar between the experimental and control groups, and in which the effects of treadmill training and/or body weight support could not be differentiated from other co-interventions, were identified and described separately.  Participants in the selected trials had to exhibit an abnormal gait pattern after suffering a stroke. Although blinding, concealment and number of withdrawals were assessed for all trials, these factors were not used as inclusion/exclusion criteria.  **Methods:**   * Selection of studies: Two review authors read titles and abstracts to eliminate obviously irrelevant studies. Another pair of review authors obtained full text versions of the remaining 246 studies and used the inclusion criteria to rate them relevant, potentially relevant or irrelevant. A third pair of review authors then analysed the relevant and possible relevant studies to determine if they matched the PICO components of the overall systematic review study question. Disagreements were resolved via discussion among all authors and/or contacting trialists for more information. * Data extraction/management: Two review authors independently extracted trial and outcome data from the selected studies, then checked the data for agreement, resolving disagreement through another review author’s arbitration or by contacting trial researchers for more information when necessary. Authors addressed possible bias in accordance with *Cochrane Handbook for Systematic Reviews of Interventions*; they independently assessed random sequence generation, allocation concealment, and blinding of assessors in all included studies according to the “Risk of bias” tool. * To measure treatment effect for outcomes expressed as continuous data for the same outcome measures, authors calculated a pooled estimate of mean difference and 95% confidence interval (CI) using original mean differences and standard deviations. For continuous data where different outcome measures were used, standardized mean differences were calculated. For dichotomous data, risk differences with 95% CI were calculated. A random-effects model was used for all analyses, indicating heterogeneity of treatment effects among studies included in the meta-analysis. * The I2 statistic was used to assess heterogeneity, and funnel plots were used to visually assess publication bias. * Authors conducted three subgroup analyses, including time between stroke and initiation of the study intervention, the intensity of training and the duration of training—but not for co-interventions in conjunction with treadmill training as they originally intended due to insufficient data. * Reviewers performed sensitivity analyses based on methodological quality of the trials that included treadmill training, with quality determined by true as opposed to quasi-randomization, concealed versus unconcealed allocation, and blinded versus un-blinded assessment. |
| **Setting** |
| Some of the included studies performed interventions in outpatient clinic settings, others in inpatient rehabilitation hospitals, and a small number in both. Some control group interventions were performed as largely self-guided home-based exercise programs. |
| **Participants** |
| * 48 studies were included in the qualitative analysis * 44 of the 48 included studies involving a total of 2658 participants were included in the quantitative analysis. 22 of these studies with 1588 participants compared treadmill training with bodyweight support to other physical therapy; 16 studies with 823 participants compared treadmill training without bodyweight support to other physical therapy; 2 studies (100 participants) compared treadmill training with body weight support to the treadmill training without body weight support; 4 studies did not specify whether they used body weight support or not. No studies compared body weight support alone to other physical therapy. Two studies’ participant data were subdivided into dependent and independent ambulators at treatment initiation and included in the corresponding subgroup meta-analyses. * All participants had suffered a stroke and exhibited an abnormal gait pattern. Authors defined stroke using the World Health Organization’s definition and defined abnormal gait pattern as demonstrating slow walking speed, deviating from normal gait kinematics, or unable to walk. * Mean age for participants in the included studies ranges from 50 to 79 years, with the majority being late-50s to mid-60s. * Mean time between stroke and initiation of study intervention for participants in the included studies ranges widely from approximately 8 days to 5 years. |
| **Intervention Investigated** |
| *Control* |
| * Most of the control groups completed some type of alternative therapy matched for time with the experimental group intervention protocol. * Type of control intervention differed between studies and included treadmill walking without body weight support, overground walking training, functional task training, sham non-task-specific home exercise program, lower extremity strengthening exercises, or no intervention. * Frequency of treatment ranged from 3 times per week to twice daily, duration of individual sessions ranged from 20 minutes to 90 minutes, and the length of intervention period (when uniform for all participants) ranged from 2 weeks to 16 weeks. |
| *Experimental* |
| * Intervention protocol for all studies included walking on a treadmill either with or without body weight support. * Frequency of treatment ranged from 3 times per week to twice daily, duration of individual sessions ranged from 20 minutes to 90 minutes, and the length of intervention period (when uniform for all participants) ranged from 2 weeks to 16 weeks. |
| **Outcome Measures** (Primary and Secondary) |
| * The primary outcome was ability of subjects to walk at the end of the intervention period (short-term effects) as well as the end of scheduled follow-up (long-term effects).   + This outcome was analysed by the dichotomous variable “dependence on personal assistance,” where “dependence” was defined as inability to walk indoors (with or without an assistive device) without personal assistance or supervision. Particular functional scale scores reported in individual studies were used to define the level of dependence of participants in that study. Criterion specifying “dependence” for particular scales are as follows: a score of 2 or less on Motor Assessment Scale, a score of 5 or less for the walking item of the Functional Independence Measure, a score of 3 or less for the ambulation item of the Barthel Index, an answer of “no” to the “walking inside, with an aid if necessary” item of the Rivermead Mobility Index, or a score of 2 or less on the Functional Ambulation Category.   + Two continuous variables were also used to analyse walking ability. The first was independent walking speed over a short distance (defined as 6-10 meters), which authors note has been established as a reliable, valid and sensitive measure of walking performance. The second continuous variable was independent walking endurance expressed as a total distance walked and measured over a long distance (using the 6 Minute Walk Test, for example), which authors supported as a reliable and valid walking endurance indicator with established reference equations. Speed and distance scores of zero were assigned if patients could not walk unless personally assisted. Gait devices were allowed for completion of these measures. * Secondary outcome measures included quality of life, ability to perform activities of daily living, and the combined outcomes of death or dependency, and institutional care or death. However, analyses were not performed on these measures as they were not reported in enough qualifying studies. * As a measure of the safety of treadmill training, authors used prevalence of adverse events during the treatment period. * As a measure of acceptance of treadmill training, authors qualitatively analysed withdrawal data or reasons for participants withdrawing from studies. |
| **Main Findings** |
| Because this systematic review involved such a large number of statistical comparisons, only the primary comparisons and the comparisons for treadmill training with body weight support versus other physical therapy or no intervention are reported in this critically appraised topic based on relevance to the focused clinical question.  In statistically examining the relative effects of treadmill walking interventions *with or without BWS* to other interventions (including no intervention), authors obtained the following results:  Walking speed:   * 35 studies (N=1891) provided data for walking velocity at the end of the intervention period. Pooled mean difference (MD) was 0.07 m/s (95% CI 0.03-0.11, P = 0.0003, heterogeneity I2 = 44%). Overall, the use of treadmill training in walking rehabilitation for patients after stroke significantly increased gait speed. * For 9 studies using exclusively participants who required assistance to walk pre-trial (N= 752), pooled MD was -0.01 m/s (95% CI -0.06-0.03, P+ 0.52, heterogeneity I2 = 0%). For this subgroup of patients after stroke, use of treadmill training for walking rehabilitation did not significantly increase gait speed. * In 26 studies using exclusively participants who could walk independently pre-trial, pooled MD was 0.11 m/s (95% CI 0.06-0.16, P<0.0001, heterogeneity I2 = 37%). Treadmill training did significantly increase gait speed compared to other therapy for this group. * Authors found a statistically significant difference in walking speed between dependent and independent walkers: X2 = 14.71, df = 1, P = 0.0001).   Walking endurance:   * 20 trials (N = 1388) provided data for walking capacity (defined as meters walked in 6 minutes). Pooled MD = 20.08 (95% CI 6.14-34.03; P = 0.005, heterogeneity I2 = 35%). Overall, the use of treadmill training in walking rehabilitation for patients after stroke significantly increased walking endurance. * For 5 trials including exclusively participants who required assistance to walk pre-trial (N = 639), pooled MD was -5.09 m (95% CI -23.41-13.22, P = 0.59, heterogeneity I2 = 0%). For this subgroup of patients after stroke, use of treadmill training for walking rehabilitation did not significantly increase walking endurance. * For 15 studies using exclusively participants who could walk independently pre-trial, pooled MD was 30.61 m (95% CI 14.02-47.20, P=0.0003, heterogeneity I2 = 30%). Treadmill training did significantly increase gait speed compared to other therapy for this group. * Authors found a statistically significant difference in walking endurance between dependent and independent walkers: X2 = 8.02, df = 1, P = 0.005).   Based on subgroup meta-analyses examining the relative effects of treadmill walking interventions *specifically with BWS* compared to other interventions (including no intervention), authors obtained the following results:  Dependence on personal assistance to walk *at the end of the intervention period*:   * 19 studies (N=1210) examined dependence on personal assistance at the end of the intervention period. Risk difference (RD) was 0.00 (95% CI -0.02-0.02, P = 0.92, heterogeneity I2 = 0%). Overall, the use of treadmill training with BWS for patients after stroke did not significantly increase chance of walking independently compared to other physical therapy interventions. * For 8 studies using exclusively participants who required assistance to walk pre-trial (N= 814), RD was -0.00 (95% CI -0.06-0.03, P+ 0.52, heterogeneity I2 = 0%). For this “dependent walker” subgroup, use of treadmill training with BWS did not significantly increase walking endurance. * In 11 studies using exclusively participants who could walk independently pre-trial (N = 396), RD was -0.00 (95% CI -0.06-0.03, P+ 0.52, heterogeneity I2 = 0%). Treadmill training with BWS did not significantly increase gait speed compared to other therapy for this group. * Authors did not find a statistically significant difference between pre-trial dependent and independent walkers: X2 = 0.01, df = 1, P = 0.94.   Walking speed *at the end of the intervention period*:   * 19 studies (N=1163) provided data for walking velocity at the end of the intervention period. Pooled mean difference (MD) was 0.07 m/s (95% CI 0.01-0.12, P = 0.02, heterogeneity I2 = 57%). Overall, the use of treadmill training with BWS in walking rehabilitation for patients after stroke significantly increased gait speed. * For 8 studies using exclusively participants who required assistance to walk pre-trial (N= 738), pooled MD was -0.01 m/s (95% CI -0.06-0.03, P= 0.52, heterogeneity I2 = 0%). For this “dependent walker” subgroup, use of treadmill training with BWS did not significantly increase gait speed. * In 11 studies using exclusively participants who could walk independently pre-trial (N = 425), pooled MD was 0.14 m/s (95% CI 0.07-0.22, P<0.001, heterogeneity I2 = 42%). Treadmill training with BWS did significantly increase gait speed compared to other therapy for this group. * Authors found a statistically significant difference in walking speed between dependent and independent walkers: X2 = 13.17, df = 1, P = 0.0003).   Walking endurance *at the end of the intervention period*:   * 10 trials (N = 869) provided data for walking capacity (defined as meters walked in 6 minutes). Pooled MD = 26.35 m (95% CI 2.51-50.19; P = 0.03, heterogeneity I2 = 60%). Overall, the use of treadmill training in walking rehabilitation for patients after stroke significantly increased walking endurance. * For 5 trials including exclusively participants who required assistance to walk pre-trial (N = 639), pooled MD was -5.09 m (95% CI -23.41-13.22, P = 0.59, heterogeneity I2 = 0%). For this “dependent walker” subgroup, use of treadmill training with BWS did not significantly increase walking endurance compared to other interventions. * For 5 studies using exclusively participants who could walk independently pre-trial (N=230), pooled MD was 56.77 m (95% CI 34.50-79.04, P<0.00001, heterogeneity I2 = 0%). Treadmill training with BWS did significantly increase walking endurance compared to other therapy for this group. * Authors found a statistically significant difference in walking endurance between dependent and independent walkers: X2 = 17.68, df = 1, P<0.0001).   Outcomes *at the end of the scheduled follow-up*: While fewer than half the number of trials in which body weight support with treadmill training was employed included outcomes data at a scheduled follow-up, results were somewhat stable over time. The changes in statistically significant results from those reported at the end of the training period are as follows:   * All pooled participants in body weight supported treadmill training, as well as the subgroup independent in walking at study onset, failed to demonstrate significantly higher gait speed compared to controls at follow-up, though their increase in speed reached significance at the end of the treatment period. * All pooled participants in body weight supported treadmill training failed to demonstrate significantly higher walking endurance at follow-up though their increase in endurance reached significance at the end of the treatment period.   Adverse events were reported for 24 trials (N = 1511), and overall, the use of treadmill training with or without body weight support in walking rehabilitation did not increase the risk of adverse events during the intervention period: RD 0.02, 95% CI -0.01-0.05, P=0.14, heterogeneity I2=51%.  Drop outs at study end were reported for 44 trials (N=2658), and overall, walking intervention using treadmill training with or without body weight support did not significantly increase risk of patients dropping out by the end of treatment (RD 0.00, 95% CI -0.01-0.02, P=0.62, Heterogeneity I2=0%) nor by the end of follow-up (11 trials, N=657, RD -0.02, 95% CI -0.08-0.04, P=0.56, heterogeneity I2=20%).  Sensitivity analysis: Removing studies which lacked adequate control for bias did not considerably impact the size of the statistically significant effect for walking speed at the end of the treatment phase when considered across all treadmill interventions for patients of all baseline walking ability levels.  Acute versus chronic phase of stroke: The use of treadmill training (with or without body weight support) for baseline independent walkers resulted in significant increases in walking speed and walking endurance regardless of whether they initiated training less than 3 months or more than 3 months after stroke. Differences in velocity between groups based on time since stroke did not reach significance.  Frequency and duration of training: The use of treadmill training (with or without body weight support) for baseline independent walkers resulted in significant increases in walking speed and walking endurance when performed 3-4 times per week or more, but did not result in significant increase in either factor when performed less than 3 times per week. Differences between groups in velocity and endurance based on frequency did not reach significance. Although independent walkers significantly increased walking speed by end of treatment periods of greater or less than 4 weeks, there was a significant difference between the speed increase for participants training for different durations, with those training 4 weeks or less experiencing a greater mean amplitude of improvement. Differences in endurance between participants training for different durations did not reach significance. |
| **Original Authors’ Conclusions** |
| Overall, treadmill training with or without body weight support offered to individuals after stroke may increase their walking speed and endurance but not enhance their ability to walk independently. In particular, individuals who are able to walk independently after stroke (but not those who require assistance to walk at the start of treatment) appear to benefit from treadmill training-based walking interventions, and their improvements in speed and endurance persist over time. |
| **Critical Appraisal** |
| **Validity** |
| This review appears to be as comprehensive as possible and of high quality. The methodological rigor of Cochrane reviews generally minimizes bias in the review process. Reviewers fully described study selection and search methods, and they included grey literature and non-English studies in their search. Funnel plots for all included trials did not indicate publication bias or systematic heterogeneity. While there was clearly heterogeneity of trial design, it is not clear to what extent these differences impacted or limited evidence quality. By limiting their search to RCTs (and quasi-random experimental designs), authors eliminated studies that would tend to be of lower methodological quality and power.  Although two of the reviewers participated in conducting and analysing one of the included studies, they ensured that a third reviewer who was not involved with this trial extracted the outcome data and described the risk of bias. Authors reported the results of their qualitative “risk of bias” analyses to identify any threat of testing and assignment bias. Of the 44 included studies, 25 described the random sequence generation method adequately, 20 appropriately described the method of concealment of allocation, and 21 blinded the outcomes assessors to group allocation. The sensitivity analysis used to determine the impact of methodological quality on the effectiveness of the intervention indicated that benefits of treadmill training, particularly increased gait speed, were well-preserved when those trials were removed which failed to meet these “risk of bias” criteria. Authors concluded that methodological quality is generally moderate for the included studies, although they noted that a few limitations generally threaten trials investigating treadmill training with and without body weight support: inability to blind therapists and subjects, contamination (or providing the intervention to the control group) and co-intervention (the same therapist providing additional care to either experimental or control group unintentionally).  In handling data from individual studies, authors used a random effects model of analysis since parameters of interventions varied between studies. They also reported pooled effect sizes and risk differences/ratios for all major outcomes via several subgroup analyses based on heterogeneity of treatment design and participantsusing individual subject data. Finally, authors compared their findings with other available comparable reviews; theirs was a more comprehensive review. |
| **Interpretation of Results** |
| Based on this recent systematic review and meta-analysis, use of treadmill training with body weight support did n*ot* increase the chance of people after stroke walking independently but *did* significantly increase their walking velocity and endurance when compared with use of physical therapy interventions other than treadmill training. However, benefits in gait speed and walking endurance were only observed for those participants who were able to walk independently pre-trial. No benefits were found for individuals who required assistance to walk at the start of treatment.  Effect Sizes and Clinical Importance of Results:   * Overall, treadmill training with or without body weight support produced statistically significant higher walking speed of 0.07 m/s, which is the same magnitude as the previously reported standard error of measurement or minimal detectable change for people after stroke, suggesting this is not a clinically important improvement. * Since the minimal important clinical difference was previously determined within 95% certainty to be between 0.15-0.25 m/s for people following stroke, the subgroup of independent walkers whose increase in gait speed reached 0.11 m/s did not realize clinically important improvement. * Overall, treadmill training with or without body weight support produced statistically significant higher walking endurance of 20 m, which is only slightly greater than the previously reported standard error of measurement (or minimal detectable change) of 18.6 m for people after stroke, suggesting this is not a clinically important improvement. * Since the minimal important clinical difference was previously determined within 95% certainty to be between 37-66 m for people following stroke, the subgroup of independent walkers whose increase in gait endurance reached 30 m did not realize clinically important improvement. |

**(3)** Description and appraisal of Optimal Outcomes Obtained with Body-Weight Support Combined with Treadmill Training for Stroke Subjects: a randomized trial by Barbeau et al.

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| **Aim/Objective of the Study/Systematic Review:** |
| The aims of this study are to 1) determine characteristics of stroke patients most likely to benefit from body weight-supported treadmill training, 2) explore the extent of carryover of benefit from treadmill training (with or without body weight support) to overground walking and 3) to identify variables most likely to influence recovery of walking. |
| **Study Design** |
| * A single centre, assessor-blinded randomized controlled trial. * Prior to block randomization to experimental and control groups, participants were stratified according to initial ambulatory status level: low or high. Low ambulatory status was defined as nonambulatory or requiring maximum assistance to walk. High ambulatory status was marked by the need for moderate or minimal assistance to walk OR by independent walking with or without supervision but still with residual gait abnormalities. * Methods of random sequence generation and concealment allocation were not specified by authors. * Outcomes measures were collected before the initiation of training, upon completion of the 6-week training protocol, and at a 3- month follow-up. No information was provided regarding where assessments were   conducted.   * Statistical analyses: Differences in the 6 clinical outcome measures (treadmill and overground walking speeds, treadmill and overground walking endurance, balance and motor recovery) across the two treatment groups were determined using a 2-way analysis of covariance (ANCOVA) with a repeated measure on one factor. Group (BWS, non-BWS) was the independent variable, time (post-intervention, follow-up) was the second factor, and the pretraining score was the covariate. |
| **Setting** |
| Inpatient rehabilitation hospital (Jewish Rehabilitation Hospital, Laval, QC) |
| **Participants** |
| * A convenience pool of 375 patients admitted to the inpatient hospital named above between October 1992-January 1995 for physical rehabilitation after stroke were reviewed as candidates for inclusion. Mean age: 69.2 years (range, 27-93 years). Gender: 45.6% female. * 237 patients failed to meet inclusion criteria. 6 were excluded because the treadmill was overbooked, and 8 more because higher skilled ambulators were not sought at one point. 24 refused participation. * Inclusion criteria for subjects: diagnosis of right or left cortical stroke, unable to walk with normal gait pattern, free of severe cardiac problems; no comorbid conditions for which treadmill training is contraindicated; free of cerebellar, bilateral or brainstem cerebral vascular disease; no language, cognitive, behavioural or psychiatric disease impeding ability to understand simple commands; anticipated length of stay >4 weeks; onset of stroke <6months prior; new admission (versus readmission) to the hospital; ambulated prior to stroke. * 100 total participants from the original pool were recruited to the study and provided informed consent. Experimental group (EG): N = 50. Control group (CG): N = 50. Number of participants who completed the training protocol: EG N=43, CG N=36. * Mean age: EG 66.5 (12.8), 27-87 years; CG 66.7 years (10.1), 44-84 years * Gender--F/M (%): EG 19/31 (38%/62%); CG 22/28 (44%/56%) * Side of lesion—R/L (%): EG 20/30 (40%/60%); CG 29/21 (58%/42%) * Total comorbidity: EG 2.8 (1.4), 1-6; CG 2.9 (1.6), 1-7 * Delay onset of stroke to study in days: EG 68.1 (26.5), 27-138 days; CG 78.4 (30), 33-148 days * At pre-training baseline, groups were similar on all key demographics listed above as well as performance on outcome measures of balance, motor recovery, and overground walking speed and endurance. Groups were also similar in baseline measures of depression and cognitive status.   + *Note: Unless otherwise indicated, values are expressed as mean (SD), range* * Of the 100 participants, 21 dropped out, 7 from the experimental group and 14 from the control group. Comparison between dropouts and those who completed all 24 training sessions revealed that although those who withdrew did not differ with respect to disability indicated by baseline outcome measures, the dropouts tended to be elderly women with multiple comorbidities. * Available for 3-month follow-up: EG N=29; CG N=23 patients |
| **Intervention Investigated** |
| *Control* |
| Control subjects trained on a treadmill. Although they wore the harness for safety and to ensure similar experimental conditions, they received no body weight support (BWS).  Controls trained 4 times per week for the 6 week trial duration with the assistance of 1 or 2 physical therapist (PT) supervisors, depending on need and level of impairment. One PT straddled the treadmill behind the patient to facilitate proper trunk alignment and weightshift during training. The other PT stood beside the hemiparetic leg to facilitate stepping and lower limb control during stance and swing phases.  The patient walked a maximum of 3 trials for a total duration of no greater than 20 minutes per session. Subjects’ heart rates were monitored before and after each trial to ensure values did not exceed a threshold per physician recommendations.  Treadmill speed was started at 0.0 km/h and increased by increments of 0.1 km/h. Subjects were initially allowed to grip a horizontal bar attached to the front of the treadmill for stability. Treadmill speed was increased once subjects’ gait improved (the subject could maintain upright posture and shift weight limb to limb during loading while walking), at which point they were also trained to walk without using the treadmill horizontal support bar to further challenge balance and postural responses.  In addition to gait training, all participants received regular, weekday physical therapy. Details regarding the degree of standardized versus individualized duration, intensity and content for these weekday physical therapy sessions are not provided. |
| *Experimental* |
| The treadmill training protocol for the BWS support group was identical to the no-BWS group described above with the following exceptions related to additional use of the body harness for partial unloading. Experimental subjects were also provided BWS, supplied by an overhead harness consisting of a pelvic belt secured around the hips and 2 thigh straps with anterior and posterior attachments to the pelvic belt. The harness in turn was attached to a suspension system with a force transducer providing a signal indicating the amount of body weight supported.  At the initiation of training, patients walked with 10%, 20%, 30% and 40% BWS; the therapist selected the lowest percentage (up to 40% total body weight) that enabled straight trunk and limb alignment and transfer of weight onto the hemiplegic limb. Each participant’s initial BWS percentage was progressively decreased as the patient’s walking ability and gait pattern improved. BWS was augmented as necessary in some cases in the first few sessions following increase in treadmill speed or walking without holding onto the bar, but the percentage BWS was again decreased as the patient adapted and performed with less difficulty. |
| **Outcome Measures** (Primary and Secondary) |
| **Primary Outcome Measures (to determine impact of BWS):**   * Balance was compared across groups through use of the Berg Balance Scale (BBS). This measure evaluates 14 different sitting and standing activities, each scored on a 5-point scale, with a maximum possible score of 56 where higher scores indicate better balance. * Motor recovery was assessed using the lower-extremity version of the STroke Rehabilitation Assessment of Movement (STREAM), which examines basic mobility and voluntary limb movement via 25 items each valuated on a 4-point or 2-point scale. The maximum score is 55; the higher level of function exhibited, the higher the score. * Participants walked the length of a 10 meter walkway, with the middle 3 meters timed using a stopwatch, as a measure of overground walking speed measured in meters/second. They were allowed to use any required walking aids. When a participant exhibited sufficient endurance, he/she repeated the 10 meter walk 3 times and the speed was recorded as the average of the 3 trials. To determine comfortable treadmill walking speed, subjects walked as the speed was slowly increased until patients shared their perception that a comfortable speed had been reached. The speed indicator on the treadmill was covered during this procedure. * Overground walking endurance was measured by inviting patients to walk back and forth along the 10-meter walkway using any needed walking aids until unable to continue or a maximum distance of 320 meters was reached. Treadmill walking endurance was measured as the total time a subject walked on the treadmill during a session up to a maximum of 20 minutes.   **Measures of Potential Confounding Variables:**   * Age, gender, side of lesion, time since stroke, previous strokes and other cobmorbidities were extracted from medical records. * Cognitive status was measured using the Pfeiffer Short Portable Mental Status Questionnaire, a 10-item measure with higher score indicating better functioning. Scores were not provided for patients with aphasia-related communication problems. * Depression was assessed using the 10-item version of the Zung Self-Rating Depression Scale. Scores greater than 50 out of a possible range from 25 to 100 indicate depression. |
| **Main Findings** |
| * When post-hoc stratification of subjects was performed according to pretraining scores, significant change on all clinical outcome variables was observed for the clinical outcome measures of overground speed, overground endurance, balance, and motor recovery. * A group effect was also observed. Subjects with baseline scores indicating more severe impairments showed changes in walking speed, overground endurance, balance and motor recovery that were significantly greater than changes seen in subjects who were less impaired on each of the measures pretraining. However, point values and P-values for these analyses are not supplied, with comparisons presented only visually through graphs. * No significant group x time interaction effects were found through ANCOVA analyses for any of the outcome measures for any of the subgroups determined through post-hoc stratification based on pre-training outcome measure scores or age. * While pre- and post-training walking speeds were greater on the treadmill compared to overground for both BWS and non-BWS groups, the BWS group demonstrated greater carryover of treadmill walking speed to overground speed compared to the non-BWS group. Again, however, point values and P-values for these analyses are not supplied, with comparisons presented only visually through graphs. * When stratified by age (20-65 years and 65-86 years), the difference between groups in walking speed was significant (p<.03) for the older group compared with the younger group (p<.457). * The side of lesion did not significantly impact walking speed change in either group separately nor when combined. |
| **Original Authors’ Conclusion** |
| Authors concluded that treadmill training with partial body weight support for patients following stroke resulted in better walking and postural abilities than treadmill training without with full weight bearing. They also state that subjects with stroke who demonstrate more severe baseline gait impairments and who are older appear to reap the greatest relative benefit from body weight support. Authors report finding evidence to support that gait speed improvements on the treadmill transfer to overground training. Lastly, since 79% of the participants were able to complete the 6-week walking training protocol on the treadmill with or without BWS, authors suggest treadmill training is well-accepted by individuals after stroke. |
| **Critical Appraisal** |
| **Validity** |
| * PEDro Scale score: 5/11 based on Eligibility criteria: Yes; Random allocation: Yes; Concealed allocation: No; Baseline comparison: Yes; Blind subjects: No; Blind therapist: No; Blind assessors: Yes; >85% participant outcomes: No; Intention-to-treat analysis: No; Between-group comparison: Yes; Point estimates and variability: No. * Participants and therapists administering the locomotor training interventions were not blinded and therefore could have biased the outcomes. * It is not clear how participant withdrawal from the study or missing data were handled statistically to preserve random allocation and baseline similarity between groups. Authors only shared that dropouts tended to be elderly women of greater overall comorbidity who did not differ significantly from subjects who completed the training protocol; their actual reasons for withdrawal were not provided. Also, no report on adverse effects is included to allow interpretation of relative safety and feasibility of the two group interventions. * Although the overall time on the treadmill was consistent (20 minutes maximum) across groups, authors do not mention therapists recording the length of rest breaks required by subjects in both groups per session and thus overall proportion of time spent in resting versus practicing stepping. It is possible that a significant difference in overall step practice across training sessions is overlooked given the lack of attention to this factor in the protocol. * The fact that all patients were recruited from the same inpatient treatment facility could limit the sample’s ability to represent the larger stroke population. It is possible this facility caters to a particular demographic in SES, income, insurance coverage, or race/ethnicity which may limit applicability to all cortical stroke patients with hemiplegia. * As this is a secondary analysis of an earlier trial (Visintin 1998), the study was likely powered for the primary analyses (reported elsewhere), and it may be underpowered for the analyses conducted in this study, making it more difficult to detect a clinically significant effect. |
| **Interpretation of Results** |
| * The findings of the original trial favour intensive treadmill training with partial body weight unloading over treadmill training with full weight bearing for patients seeking inpatient rehabilitation within 6 months of stroke. The difference between the two groups in degree of change on outcomes of interest reached statistical significance with greater improvement in balance as well as endurance and speed of walking observed by those offered body weight support. * Although individuals of a wide range of impairment severity benefitted more from BWS in combination with treadmill training in the initial study, the results of this secondary analysis of trial data suggest that patients with more profound baseline walking deficit post-stroke may derive the greatest benefit from treadmill training with BWS versus without BWS in terms of walking speed and endurance, balance, and motor function. However, no stratified group by time effects were statistically significant on any of the outcome variables. * Since the authors did not include the group means at the different time points of outcomes measurement from which they calculated group by time interactions, it is impossible to estimate the effect size for differences between the BWS or no-BWS treadmill training group. Thus clinical judgments from these results are limited regarding meaningfulness of change to justify recommending the interventions for individual clients after stroke or justifying the cost of purchasing harness equipment in addition to treadmills or both items for an inpatient rehabilitation facility. |

**IMPLICATIONS FOR PRACTICE and FUTURE RESEARCH**

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| All evidence reviewed in this critical appraisal suggests that body weight supported treadmill training (BWSTT) is both safe and generally well-accepted for patients with hemiparesis after stroke. The two reviewed RCTs suggest that BWSTT is at least as effective as overground training or treadmill training without body weight support in improving patients’ walking ability, with a tendency towards leading to greater improvements. The meta-analyses performed through a more recent systematic review conducted by Mehrholz et al (2014), which included consideration of both of these trials, found no statistically significant benefits of BWSTT over other therapies for individuals after stroke unable to walk at baseline, which supports the findings of Ada et al (2010). However, reviewers determined that statistically but not clinically significant improvements in walking speed and endurance were observed in people able to walk independently before starting the treadmill training intervention.  Considered together, these findings suggest that while BWSTT can help an individual like the patient described in the clinical scenario safely achieve independent walking overground as demonstrated by Ada et al (2010), it is not necessarily *more* likely to help him/her reach this goal than overground walking training or other physical therapy interventions. As long as the intensity of training is sufficiently high, BWSTT and overground walking may be considered equally effective, and decisions regarding which to use with an individual patient of the type described in the clinical question should take into consideration such factors as equipment and staff available in the clinic, the degree of difficulty mobilizing the patient overground, and the patient’s preference. For patients recovering from stroke, BWSTT offers more clear benefits over other techniques if the patients are already able to walk independently, regardless of how far they are able to walk or if they require assistive devices, and if the aim of therapy is to increase walking speed and endurance.  The studies also imply some additional considerations in using BWSTT in the clinic. First, the fact that 3% of BWSTT participants in the study by Ada et al (2010) experienced anxiety from being on a treadmill severe enough for them to withdraw suggests therapists should fully explain/demonstrate the method and confer with patients regarding their comfort level as a routine part of decision-making between using this or other interventions. Second, a significant portion of all scheduled BWSTT sessions that were missed in this study were due to the treadmill not working, which suggests therapists who choose to use BWSTT need to prepare for mechanical failure with a solid “backup” plan supported by evidence of conferring similar clinical benefits. Barbeau et al (2003) reported that patients who withdrew from the study tended to be older women with greater comorbidity compared to other participants without explaining their reasons for withdrawal; therapists may therefore be especially cautious in recommending BWSTT to this population. Finally, Mehrholz et al (2014) demonstrated that the most clinically meaningful benefits of treadmill training were realized by patients after stroke with frequency of treatment 4 or more days per week, while no additional benefit was conferred over other interventions with training less than 3 days per week. The greatest effects of treadmill training are also to be expected within the first three months following stroke. Therefore, therapists should take into consideration that the greatest benefits of BWSTT may be easier to realize in an inpatient rehabilitation centre or hospital where patients are treated daily and are more likely to be in the subacute phase of stroke than in an outpatient setting. If used in an outpatient setting, therapists should prescribe at least 3 days per week of training in the plan of care after discussing the feasibility with patients and their families.  Another significant factor for clinicians considering use of BWSTT to consider is cost-effectiveness based on the required equipment and staff. While the appraiser was not able to determine the number of inpatient and outpatient physical therapy practices in the Triangle area or state of North Carolina that possess treadmills and body harnesses for unloading patients during gait training, clinical experience has suggested they are more commonly seen in practices with a high neurological patient population such as hospital-based inpatient and outpatient rehabilitation centres. Therapists interested in using BWSTT should consider the modest advantages of BWSTT over other interventions demonstrated in the current literature for individuals after stroke and research its relative effectiveness for other patient populations they treat commonly (e.g., spinal cord injury, Parkinson’s) before purchasing equipment if their clinic does not already have this system. Morrison and Backus (2007) thoroughly examine the financial feasibility of delivering BWSTT for a spinal cord injury patient in a hospital-based outpatient facility. They pointed out in their analyses that costs increase with purchase of more expensive treadmill and harness models, more assisting staff per patient and with a payer mix including more Medicare/Medicaid beneficiaries compared to privately insured individuals. Therapists should examine this study and carefully consider their own practice in conducting their own cost-benefit analyses.  In the future, more trials of high methodological quality and large sample size should be conducted to compare the combination of BWSTT and overground walking with each separately and with other therapy interventions, and should also examine baseline independent and dependent ambulators’ responses to these interventions. More quality studies should include baseline dependent walkers and examine the achievement of independent walking as an outcome measure in addition to commonly measure walking improvements such as speed and endurance. Since protocols of trials examining the impact of BWSTT have to date varied widely, further investigation of treadmill training interventions should examine the impact of different frequencies and durations of training as well as use of handrails on walking outcomes. |

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